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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,650	09/23/2003	Douglas S. Cali	816020-100041US	2078
34026	7590	06/08/2006	EXAMINER	
JONES DAY 555 SOUTH FLOWER STREET FIFTIETH FLOOR LOS ANGELES, CA 90071			MATTHEWS, WILLIAM H	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 06/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/668,650	CALI ET AL.
	Examiner William H. Matthews (Howie)	Art Unit 3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 February 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 3-9,13,16-28,30-32,35 and 36 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2,10-12,29,33,34 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## DETAILED ACTION

### ***Election/Restrictions***

1. Applicant's election without traverse of Group II and Specie A (figure 4a-5) in the reply filed on February 28, 2006 is acknowledged. In the Restriction Requirement, Group I was directed to heart valve devices and Group II was directed to methods of using heart valves. It is believed Applicant intended to elect a product of manufacture which is Group I rather than Group II since Applicant has withdrawn all claims drawn to methods. Applicant listed claims 30-32 and 35-36 as the only claims non-readable on the elected species. Examiner further finds claims 3-9,13,16-28 as non-readable on figures 4a-5 because the subject matter described explicitly in claims 3,9,13,16,22, and 26 are not disclosed as features of figures 4a-5.

2. Claims 3-9,13,16-28,30-32,35,36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species or invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2-28-06.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 11 and 33,34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 depends from claims 1 and 10

which each recite "scalloped portions", therefore it is unclear as to what "the scallops comprise longitudinally extending portions" of claim 11 encompasses. Regarding claims 33 and 34, it is unclear as to what "the midpoint of each of the leaflets" defines.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1,29,33,34 are rejected under 35 U.S.C. 102(a) as being anticipated by Jansen WO 02/24117 (english translation may be found in USPN 6,780,200).

Jansen disclose in abstract, and figures 1,5,6 a replacement heart valve comprising a valve body having two commissural attachment locations and an annulus having a saddle shaped portion defined by high peripheral portions 18,19 and low peripheral portions therebetween. Figure 5 shows an anterior side (the right side) having a length longer than a posterior side of the device. Regarding claim 33, leaflets are sewn to the body along edges 11,12 and the diameter of the device (line 20 of figure

6 and described at final 3 lines of page 5) may be 10mm. Therefore it is clear from the figures that a distance in the second direction as claimed is about 1-3mm.

7. Claims 1,2,10,12,14,29 are rejected under 35 U.S.C. 102(e) as being anticipated by Lane US PN 6,371,983.

Lane disclose in figures 1-3,7, and 9-11 a replacement heart valve comprising a body having scalloped inlet and outlet portions, plurality of leaflets, high and low peripheral portions, and figure 9 depicts one of the high peripheral portions is higher than the other (as well as an anterior side having a longer length than a posterior side). Lines 17-33 describe seams for the leaflets.

#### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lane US PN 6,371,983 as applied to claims 1, 12 and 14 above, and further in view of Myers et al. US PN 6,682,559.

Lane discloses the limitations of claim 15 but lack the express written disclosure of sewing the leaflet edges in opposing fashion such that a slight biasing towards a

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closed position is achieved. Myers et al. teach in column 8, lines 39-67 and figures 4-5 that it is well known to attach opposing leaflet edges in order to provide a slight biasing towards the closed position.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention disclosed by Lane to include opposing leaflet edge seams as taught by Myers et al. in order to provide a slight biasing towards the closed position.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



William H. Matthews (Howie)  
Examiner  
Art Unit 3738